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December 27, 1999

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: 21 CFR Parts 210, 211, 820, 1271

Suitability Determination for Donors of Human Cellular and Tissue-Based Products

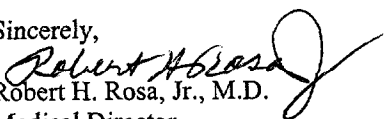
Dear Madam/Sir:

The Florida Lions Eye Bank has operated efficiently since the passage of Florida statute 732.99185 with the cooperation of South Florida Medical Examiners to provide more than 32,000 corneas totally free of charge to South Floridians over the past 38 years. The Florida Lions Eye Bank is a charitable organization which has managed to operate without charging processing fees for nearly 40 years through donations and income from a trust fund. Since its charter in 1962, the main goal of the Florida Lions Eye Bank has been to provide the gift of sight to South Floridians through corneal transplantation. Since 1977, the majority of our useable corneal tissue has been obtained from the county medical examiner offices in South Florida. During this time, we have never encountered any evidence of transmission of a neurodegenerative disease such as Cruetzfeldt Jakob Disease to any corneal recipients.

The proposed ruling to require a donor medical history interview for all corneal donors would, if passed, have a significant negative impact on the Florida Lions Eye Bank and on the supply of quality corneal tissue for patients in South Florida. Based upon the prevalence of Cruetzfeldt Jakob Disease and the typical age of the medical examiner donor, the proposed rule is not likely to prevent the spread of communicable diseases, in particular Cruetzfeldt Jakob Disease. The time that it would take to locate and interview the next of kin or someone "knowledgeable about the donor's medical history and social behavior" would delay and impede the time-limited process in obtaining surgical quality tissue for South Floridians awaiting corneal transplantation.

I would respectfully request that the FDA exempt corneal and scleral tissue from the proposed ruling until sufficient and adequate research and statistical surveys have proven that such a ruling would have a definite impact on the spread of communicable disease, in particular Cruetzfeldt Jakob Disease. Until such studies are conducted and/or a blood test for Cruetzfeldt Jakob Disease is available, I believe that the Florida Lions Eye Bank should continue to provide heretofore a safe supply of approximately 1,000 corneas to South Floridians each year totally free of charge. This charitable service provided by the Florida Lions Eye Bank has saved the Medicare Program, the U.S. government, and tax payers more than \$1,000,000 a year. Therefore, I respectfully request that the FDA exempt corneal tissue taken under state law at the Medical Examiners Office from the requirement of a donor medical history interview.

Sincerely,


Robert H. Rosa, Jr., M.D.
Medical Director
Florida Lions Eye Bank

Cc: Senators: Bob Graham, Connie Mack

Representatives: Dan Miller, Dave Weldon, Carrie Meek, Ileana Ros-Lehtinen, Robert Wexler, Joe Scarborough, E. Clay Shaw, Jr., Alcee Hastings, Tille Fowler, Karen Thurman, Cliff Stearns, John Mica, and Bill McCollum.

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